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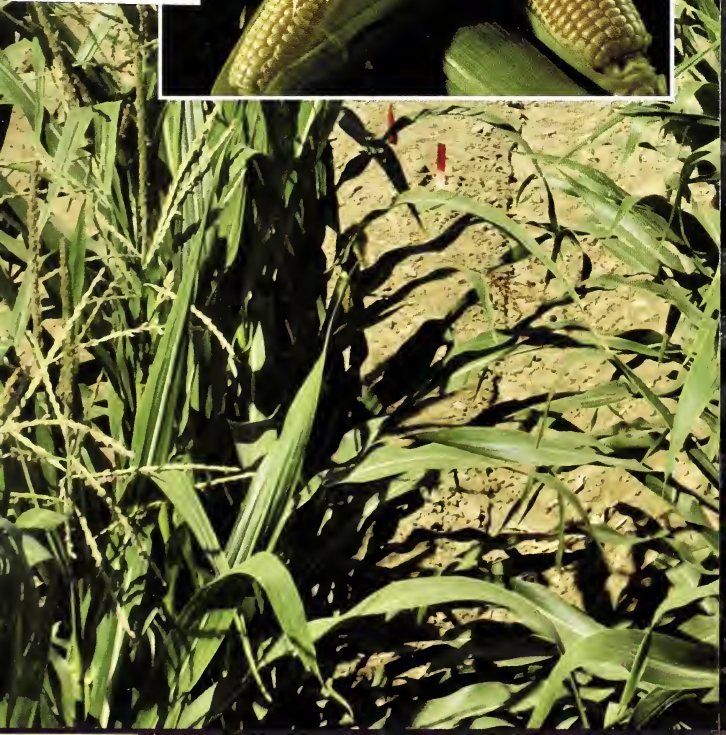


United States Department of Agriculture
Animal and Plant Health Inspection Service
Program Aid No. 2120

APHIS and Biotechnology

**Protecting Plant Health Through
Rigorous Regulation of Genetically
Engineered Organisms**

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APHIS' BIOTECHNOLOGY MISSION

To protect and enhance America's agricultural and natural resources using a dynamic, science-based regulatory framework to ensure the safe importation, interstate movement, and environmental release of genetically engineered organisms.

APHIS regularly inspects GE field tests to monitor compliance with confinement conditions. Here, an APHIS employee inspects GE cotton.



We Protect Plant Health

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Acquisitions and Metadata Branch

Through our science-based regulatory framework, the Animal and Plant Health Inspection Service (APHIS) protects against risks to U.S. plant health by providing for the safe importation, interstate movement, and environmental release/field testing of certain genetically engineered (GE) organisms. APHIS is part of the U.S. Department of Agriculture (USDA) and has regulated GE organisms since 1987.



APHIS personnel inspecting GE corn at a field test site.

We're Part of the Coordinated Framework

Established as a formal policy in 1986, the Coordinated Framework for the Regulation of Biotechnology describes the Federal system for evaluating products developed using modern biotechnology. The three main Federal agencies responsible for regulating the safe use of genetically engineered organisms are APHIS, the U.S. Environmental Protection Agency (EPA), and the U.S. Department of Health and Human Services' Food and Drug Administration (FDA).

FDA has primary responsibility for ensuring the safety of human food and animal feed, as well as proper labeling and safety of all plant-derived foods and feeds. EPA regulates pesticides, including plants with plant-incorporated protectants (pesticides intended to be produced and used in a living plant), to ensure public safety. That agency also regulates pesticide residue on food and animal feed. APHIS, through its Biotechnology Regulatory Services (BRS) program, regulates the introduction of certain GE organisms that may pose a risk to plant health.

We're Science-Based

APHIS uses science as the foundation for sound decisions on policy, rulemaking, and regulatory approvals. Experts in scientific fields (e.g., plant pathology, botany, entomology, virology, ecology, environmental science, molecular biology, and biochemistry) assess plant pest risk and analyze environmental effects while considering the most current peer-reviewed scientific findings. APHIS bases its decisions and actions on the best science available.



Current peer-reviewed scientific data is analyzed as part of the regulatory review process.

We're Transparent

APHIS makes it a priority to be transparent in all of our procedures, decisions, and activities. On our Web site, we publish relevant environmental and regulatory documents for the GE crops we regulate. We announce regulatory actions and the availability of related documents in the *Federal Register*. The public may provide comments regarding proposed actions online at www.regulations.gov, through conventional mail, and at various public meetings. The APHIS biotechnology Web site (www.aphis.usda.gov/biotechnology/brs_main.shtml) offers access to a wide range of information, including official documents, guidance for GE developers, application status, news, and upcoming events.

The APHIS Biotechnology Regulatory System

Developers seeking to field test, move interstate, or import a GE organism must first submit detailed information to APHIS for review and receive regulatory



APHIS personnel working in the ePermits system, used to electronically process permits and notifications of regulated GE crops.

Six eligibility criteria for notification:

- 1. The GE plant is not listed as a Federal noxious weed and is not considered a weed in the area of introduction.**
- 2. The genetic material must be “stably integrated” into the plant genome.**
- 3. The newly introduced gene’s function must be known and not result in plant disease.**
- 4. The newly introduced gene’s function must not cause production of a plant pest, cause the plant to produce substances that are toxic to nontarget organisms, or be genetically engineered for the purpose of producing compounds intended for pharmaceutical or industrial use.**
- 5. The newly introduced gene must not cause the creation of a new plant virus.**
- 6. The plant must not have been modified to contain genes from animal or human pathogens.**

approval. During its review, APHIS assesses the information for potential plant health risks before the introduction can be approved. Depending on the characteristics of the GE organism, a developer either files a *notification letter* or applies for a *permit*.

The Notification Process

GE plants that meet six specific criteria (see sidebar above) undergo an administratively streamlined alternative to the permit process, known as “notification.”

As part of the notification process, applicants must provide information on the nature of the plant and introduced genes, descriptions of genetic modifications, size of the introduction, and origin and destination for movement or the location of a field test. Upon approval, notifications are valid for 1 year from the date of issue.

If a plant does not meet the eligibility criteria for notification, the applicant must follow the permitting process.

The Permit Process

The permit process applies to GE plants that do not meet all six criteria for notification and to GE organisms other than plants (e.g., insects, microbes) that fall under APHIS regulation. This process involves a more comprehensive review than notification does. In addition to the data required in the notification process, field-test permit applicants must provide a detailed description of how they will perform the test. This description must include specific measures to reduce the risk of harm to other plants, so the organisms being tested remain confined and do not persist after completion of the field test. Depending on the characteristics of the GE organism, APHIS may impose additional measures and supplemental permit conditions. Permits may be valid for 1 year or more from the date of issue.

APHIS also works closely with State departments of agriculture and federally recognized tribes to ensure that they are aware of field tests taking place within their jurisdictions and have an opportunity to apply any further safeguards at the State or tribal level.

Compliance With Regulations

APHIS officials perform inspections tailored to the specific requirements of the notification or permit. In addition, APHIS provides continuous education and outreach to the regulated community, including the Biotechnology Quality Management System (BQMS) Program. This program provides participants with specific tools and guidance to implement a BQMS tailored to their own needs, facilitating more effective compliance with APHIS regulations.

APHIS compliance specialists and inspectors perform targeted inspections and audits to thoroughly evaluate suspected or reported compliance infractions. The Plant Protection Act of 2000 allows substantial penalties for serious infractions, including fines of up to \$500,000 and the possibility of criminal prosecution. APHIS works closely with State departments of agriculture and other Federal agencies, including the FDA and the EPA, to ensure compliance with regulations.



APHIS requires that organizations conducting GE field trials keep detailed records on all GE seed. Here, the seeds are counted, weighed, and logged.

Petition for Determining Nonregulated Status

Under the Plant Protection Act and title 7, section 340.6 of the *Code of Federal Regulations* (CFR), if developers (applicants) can demonstrate that a GE organism is not a plant pest, they can submit a petition (request) to APHIS for a determination of nonregulated status; this status means that the GE organism is no longer subject to regulatory oversight under 7 CFR part 340. The petitioner must provide data, often gathered through confined field tests regulated by APHIS, to help inform the agency's decision. APHIS analyzes data from the petitioner, researches current scientific findings, and prepares a plant pest risk assessment (PPRA) in accordance with the Act.

APHIS also prepares documentation required by the National Environmental Policy Act of 1969 (NEPA); under NEPA, all Federal agencies must take a close look at the potential environmental impacts of their proposed actions prior to making decisions. Therefore, at the same time as it develops a PPRA, APHIS prepares either an environmental assessment (EA) or an environmental impact statement (EIS) to analyze potential environmental impacts the GE plant may have. Once complete, APHIS makes the document available to the public for comment. Overall, the petition process allows for two, and in some cases three, opportunities for public comment.

After receiving and considering all comments, APHIS determines nonregulated status if it concludes that the GE organism does not pose a plant pest risk. The GE organism is then no longer subject to the regulations and may be freely moved and planted without permits or other regulatory oversight by APHIS. Most developers will seek to obtain nonregulated status for their organism, along with completing applicable reviews at other agencies, as a practical step toward commercialization.



APHIS personnel inspecting a combine harvester used in a GE corn field test.



APHIS and Biotechnology

APHIS' authority for the regulation of biotechnology is derived from the Plant Protection Act of 2000.

If you are interested in APHIS' biotechnology program initiatives and current activities, please join our stakeholder registry to receive automatic updates and other useful information. Register at <https://web01.aphis.usda.gov/BRS/BRSWeb.nsf>.

For More Information

To find out more, please visit APHIS' biotechnology Web site at www.aphis.usda.gov/biotechnology/brs_main.shtml. If you have additional questions about permitting or regulatory activities, please call BRS at (301) 851-3886.

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This publication supersedes Program Aid No. 1841, "Biotechnology Regulatory Services: Ensuring Safety in the Development of Genetically Engineered Organisms," which was published in October 2005.